



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

April 8, 2020

Heather Bjornson-Lam  
Agent for Central Solutions, Inc.  
c/o Bjornson Regulatory Consulting LLC  
272 Hathaway Lane  
Wynnewood, PA 19096

Subject: Label and CSF Notification per PRN 98-10 – To correct the Other Ingredients and the Precautionary Statements and Basic CSF.  
Product Name: TRI-CEN  
EPA Registration Number: 211-65  
Application Date: March 20, 2020  
Decision Number: 561144

Dear Ms. Bjornson-Lam:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

The Basic CSF dated 3/19/2020 submitted with your application have been stamped “Notification” and placed in our files.

Any CSFs other than those listed above are superseded/no longer valid.

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If you have any questions, please contact Srinivas Gowda at 703-308-6354 or by email at [gowda.srinivas@epa.gov](mailto:gowda.srinivas@epa.gov).

Sincerely,



Jacqueline Hardy  
Product Manager – Team 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

(Administrative Note: The following text is required for all labeling, regardless of target market)

# TRI-CEN

## High pH Phenolic Sanitizer for Use Only in Pharmaceutical Cleanrooms

Formulated for Effective Aseptic Controlled Environment ("Clean Room") Sanitation

### Active Ingredients

Ortho-benzyl-para-chlorophenol.....	4.21%
Orthophenyl-phenol.....	2.52%
Para tertiary amyl phenol.....	2.22%
<b>Other Ingredients</b> .....	<u>91.05%</u>
	100.00%

### NOTIFICATION

211-65

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/08/2020

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

SEE BACK OR SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

Central Solutions, Inc.  
PO Box 15276  
401 Funston Road  
Kansas City, KS 66115

EPA Reg. No. 211-65  
EPA Est. No. 211-KS-1

Net contents: (XX ounces) (x Gallons)

*(Administrative Note: The following text is required for all labeling, regardless of target market)*

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with plenty of water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If inhaled</b>	<ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li><li>• Call a poison control center or doctor for further treatment advice.</li></ul>
<b>If swallowed</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give <b>any</b> liquid to this person.</li><li>• Do not give anything by mouth to an unconscious person</li></ul>
<b>HOTLINE NUMBER</b> <b>For emergency medical advice, call your local poison control center or a doctor</b> <b>Have the product container or label with you when seeking medical advice or treatment.</b>	
<b>NOTE TO PHYSICIAN</b> Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.	

Product Questions? Call 1-800-255-0262 during normal business hours (8am-5pmCST)

### **PRECAUTIONARY STATEMENTS**

Hazards to Humans and Domestic Animals

**DANGER.** Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), waterproof gloves, long-sleeved shirt, long pants and shoes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

### **USER SAFETY REQUIREMENTS**

Users must wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users must remove PPE immediately after handling this product. Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

### **PHYSICAL AND CHEMICAL HAZARDS**

Combustible. Do not use or store the product near heat or open flame

*(Use Environmental Hazards statement on containers containing  $\geq$  5 gallons of product):*

### **ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## STORAGE AND DISPOSAL

**Do not contaminate water, food, or feed by storage or disposal.**

**PESTICIDE STORAGE** - Store in a securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

**PESTICIDE DISPOSAL** - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

### CONTAINER DISPOSAL

*(Note to Reviewer: One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.)*

- Nonrefillable container. Do not reuse or refill this container.  
Offer for recycling, if available.

or

Offer for reconditioning, if appropriate

Or

Puncture and dispose of in a sanitary landfill, or by incineration.

#### **Less than or equal to 5 gallons:**

Clean container promptly after emptying.

or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

#### **Greater than 5 gallons:**

Clean container promptly after emptying.

or

Triple rinse container (or equivalent) promptly after emptying.

Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

*{For non-refillable SIMPLEMENTIX® 200 Liter Drums}*

Non-Refillable Container. Do not reuse or refill this container. Completely empty container by running pump to dispense all product left in system into application equipment. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container 1/4 full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for disposal. Repeat this procedure two more times. Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

*(For other SIMPLEMENTIX® and F style containers 1 gallon or smaller that will be incinerated)*

Completely empty container allowing the product to drain for 10 seconds after the flow begins to drip. Dispose of container by permitted onsite incinerator or by transport to offsite permitted incineration services.

If incineration is unavailable, fill the container 1/4 full with water. Shake for 10 seconds. Empty and collect rinsate into appropriate storage vessel for disposal. Repeat this procedure two more times. Follow Pesticide Disposal instructions for rinsate disposal. Then offer for recycling or dispose of in a sanitary landfill.

*{Note to Reviewer: SIMPLEMENTIX<sup>®</sup> System Containers are designed to reduce worker and environmental exposure to the concentrate. These containers are designed for aseptic mixing and handling in clean rooms for closed system mixing within the container}*

*(Administrative Note: The following text is required for all containers destined for sale and/or distribution in the State of California):*

["PROPOSITION 65 ICON"ATTENTION: This product contains a chemical known to the State of California to cause cancer"]

### **DIRECTIONS FOR USE**

**It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.**

PELIGRO: Si no puede leer en ingles, pregunte a su supervisor sobre las instrucciones de su uso apropiadas antes de trabajar con este producto.

**Non-Food Contact Sanitization:** Pre-clean surface prior to sanitization. (Mix) (Prepare) (a)] 1 ounce) (of (this product) (product name)) per 1 gallon of water use solution (or equivalent use dilution) (solution according to SIMPLEMENTIX<sup>®</sup> System Container instructions)]. Apply use solution to hard nonporous (inanimate) (environmental) surfaces using a brush, sponge, cloth, mop, auto scrubber or mechanical spray device ((hand pump) coarse pump or trigger spray device) or by immersion so as to thoroughly wet surface. For sprayer applications, spray 6-8 inches from surface. Do not breathe spray. Rub with brush, cloth, or sponge. Allow surfaces to remain wet for 5 minutes. [(Rinse) (Wipe up excess liquid (with a paper towel)) (Allow to air dry)]. Change cloth, sponge or towels frequently to avoid redeposition of soil. [(Change the solution) (A fresh solution must be prepared) (Prepare a fresh solution)] at least daily or [(more often if use solution) (when use solution)] becomes visibly [(dirty) (soiled) (diluted)].

{or} [Add 1 ounce TRI-CEN to the gallon of water. Remove heavy soil or gross filth then apply solution with a mop, cloth, sponge, or hand pump trigger sprayer, so as to wet the surface thoroughly. Allow to remain wet for 5 minutes and then let air dry. If higher detergency is desired, increase dilution to 2 ounces per gallon of water. Prepare a fresh solution for each use.]

TRI-CEN is acceptable for use by pharmaceutical and biotechnology industries. For use on hard, inanimate surfaces in aseptic filling and gowning rooms, general manufacturing areas, or on machinery, tables, counters, laminar flow benches, floors, walls, stainless steel, glazed porcelain, glass, and chrome.

*(Alternative label text for center panel):*

Product and container sterilized and distributed by \_\_\_\_\_.

Sterile pharmaceutical clean room formula.

**TRI-CEN** is a phosphate free detergent

## MARKETING CLAIMS AND STATEMENTS

TRI-CEN may be used on any hard, inanimate surfaces such as walls, floors, door handles, counter tops, table tops, sinks, waste containers, lockers, desks, and other hard, nonporous surfaces.

When used as directed, TRI-CEN may be used on hard, nonporous surfaces, materials, and components such as:  
Metals: Stainless steel, chrome plated steel, brass, copper, & aluminum), Plastics: Fiberglas™, Formica™, nylon, ABS, Lexan™, Plexiglass™, acrylics and vinyl, glazed porcelain, glass, glazed ceramic tile, latex, enamel & epoxy painted surfaces, Vinyl, rubber, terrazzo, marble, glazed ceramic and quarry tile floor surfaces, Urethane, lacquer, and shellac wood finished surfaces, Other surfaces not harmed by water based cleaners.

TRI-CEN is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC#6538) and *Klebsiella pneumoniae* (ATCC# 4352) in 5 minutes.

*(Administrative Note: The following text is optional for labeling destined for the SIMPLEMIX® System Technology, closed system dilution mixing system.)*

SIMPLEMIX® System Technology for closed system mixing of pre-measured concentrate and water. *{To be used on applicable container}*

SIMPLEMIX® use solution from pre-measured ingredients in this container. Accurate every time. *{To be used on applicable container}*

SIMPLEMIX® convenient self-contained mixing system for use solution without measuring. *{To be used on applicable container}*

SIMPLEMIX® (self-contained bottle/drum design holding pre-measured concentrate/water portions to yield, after mixing, exact use solution of a specified final volume.) *{To be used on applicable container}*

## SIMPLEMIX<sup>®</sup> SYSTEM CONTAINER SYSTEM INSTRUCTIONS:

### {Trigger Spray Bottle} lid label}

1. **To prepare use solution, open cap.**
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Move spray nozzle to open position.
7. Follow directions for use on label.} or

### {Gallon Size Bottle} lid label}

1. **To prepare use solution, open cap.**
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.} or

### {200 Liter Drum} lid label}

**(Note: To be used with customer supplied pump.):**

1. **Close all valves.**
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4
5. START pump to empty cubic container
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense - Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on label.}

*{Administrative Note: To appear as label end panel for customer use on containers; convenience item.}*

<b>User Information</b>
Date Opened/Operator: <input type="text"/>
Expiration Date: <input type="text"/>
Area: <input type="text"/>

*(Administrative Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)*

**{1 Gallon SimpleMix}**



**{16 Ounces SimpleMix}**



*{Administrative Note to Reviewer: Logo to appear on SIMPLEMENT SYSTEM packages.}*

